Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

Comparative study of combined the effect of Cucurbita pepo L. oil and 1% silver sulfadiazine ointment with the control group on wound healing and severity of second degree burn pain in children 2-7 years

Protocol summary

Study aim

Determining the combined the effect of Cucurbita pepo L. oil and 1% silver sulfadiazine ointment with the control group on wound healing and severity of second degree burn pain in children 2-7 years

Design

The current research is a clinical trial study with a control group, with parallel groups, double-blind, random allocation, phase 3 on 98 eligible patients, who will be divided into two intervention and control groups using the random allocation (block) method.

Settings and conduct

This research is conducted on eligible children aged 2-7 years with second degree burns hospitalized in the burn department of Ayatollah Kashani Educational-Treatment Center, Shahrekord University of Medical Sciences, in compliance with all ethical conditions. Before the intervention, questionnaires are completed by all samples. In the intervention group, for the preparation of pumpkin seed oil, prepared Cucurbita pepo L. oil from Zardband company will be used, which is consistent with the mentioned study method and approved by the Ministry of Health. For the control group, 1% silver sulfadiazine ointment will be provided from the reputable Sina Daru company in the form of 50 gram tubes. In this study, patients, researchers, nurses and the person responsible for the analysis will not know the type of intervention for each person or group.

Participants/Inclusion and exclusion criteria

Children with second degree burns, 2 to 7 years old

Intervention groups

The studied patients are bandaged with pumpkin seed oil and silver sulfadiazine 1% once a day for a period of 14 days. The experimental group is treated with Cucurbita pepo L. oil and the control group is treated only with 1% silver sulfadiazine.

Main outcome variables

Face, Legs, Activity, Cry, Consolability scale is used to evaluate pain and Bates-Jensen Wound Assessment Tool is used to evaluate degeneration or healing of burn wounds.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190120042436N5**
Registration date: **2023-01-29, 1401/11/09**
Registration timing: **prospective**

Last update: **2023-01-29, 1401/11/09**
Update count: **0**

Registration date

2023-01-29, 1401/11/09

Registrant information

Name

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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-09, 1401/11/20

Expected recruitment end date

2023-06-10, 1402/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of combined the effect of Cucurbita pepo L. oil and 1% silver sulfadiazine ointment with the control group on wound healing and severity of second degree burn pain in children 2-7 years

Public title

Comparative study of combined the effect of Cucurbita pepo L. oil and 1% silver sulfadiazine ointment on wound healing and severity of second degree burn pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The cause of thermal burns Consent to participate in the study Age 2 to 7 years Second degree burn and below 20% and thermal type Burns in the hands and feet except the fingers Do not wash excessively with water and detergents Not having diseases that weaken the immune system The child's face is healthy and does not suffer from any congenital malformation, especially in the organs and face, and does not have trauma in the organs

Exclusion criteria:

Lack of parental consent Creating an active infection at the site of the lesion Use of topical immunosuppressants within four weeks before starting treatment Local infection Any vascular disease of the brain, cardiovascular Patients needing a skin graft for treatment

Age

From **2 years** old to **7 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **98**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible children are selected through non-probability (available) sampling, but they are assigned to one of the two groups of intervention exercises and the control group in the form of random block allocation. The random allocation of blocks will be in such a way that according to the number of studied groups, which consists of two groups consisting of group 1 (intervention) and group 2 (control), the number of blocks will be calculated based on the factorial law, that is, 2 = 1 * 2 = 2! . The possible arrangement modes of the participants from each group in each block are indicated by the label A representing group 1 (intervention), B representing group 2 (control). Therefore, there are 2 blocks for random allocation, where there are 2 participants in each block, one person from each group, but their order is different. Block sampling will continue until the number of samples is completed. It should be noted that since there are 2 samples in each block, the number of selected samples will be the same in both groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the patients are informed that they may be placed in one of the intervention or control groups, and naturally they will receive the medicine related to the same group. In addition, the main researcher and the nurse who is responsible for the care of the patients, the person responsible for collecting the data and those who evaluate the outcome and the person responsible for the analysis will not know the type of intervention for each person or group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Yasuj University of Medical Science

Street address

Shahid Motahari Blvd., Yasuj, Kohgiluyeh and Boyer-Ahmad Province

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7591741417

Approval date

2023-01-04, 1401/10/14

Ethics committee reference number

IR.YUMS.REC.1401.161

Health conditions studied

1

Description of health condition studied

Burn of second degree

ICD-10 code
T30.2
ICD-10 code description
Burn of second degree, body region unspecified

Primary outcomes

1

Description
Wound healing score of Bates-Jensen Wound Assessment Tool
Timepoint
The first session before the start of treatment, the third day, the seventh day and the day of the clear start of epithelization, the day of repair and the fourteenth day after the start of treatment
Method of measurement
Bates-Jensen Wound Assessment Tool for healing of burn

2

Description
pain severity
Timepoint
The first session before the start of treatment, the third day, the seventh day and the day of the clear start of epithelization, the day of repair and the fourteenth day after the start of treatment
Method of measurement
Face, Legs, Activity, Cry, Consolability scale (FLACC scale)

Secondary outcomes

1

Description
pain degeneration
Timepoint
The first session before the start of treatment, the third day, the seventh day and the day of the clear start of epithelization, the day of repair and the fourteenth day after the start of treatment
Method of measurement
Bates-Jensen Wound Assessment Tool

Intervention groups

1

Description
Intervention group: The studied patients are dressed with pumpkin seed oil by the researcher once a day for a period of 14 days. The experimental group is treated with pumpkin seed oil. In this way, after washing the wounds daily with normal saline, in second-degree superficial wounds that usually have a complete blister, without removing the blister in the experimental group, a layer of pumpkin seed oil with a diameter of 5 mm will be placed on the wound and It is a dressing. In a second degree deep wound where the blisters are usually destroyed, after removing the blisters and dead tissues and washing the wound surface with normal saline in a sterile way and placing a layer of pumpkin seed oil with a diameter of 5 mm on the wound, a bandage is applied. be made patients in six stages; The first session before the start of treatment, the third day, the seventh day and the day of the clear start of epithelization, the day of recovery and the fourteenth day after the start of treatment are evaluated, and the day of the clear start of epithelization and the start of the repair process will be recorded for each patient. To check the condition of the wound, they are evaluated during the study and every time the dressing is changed. If any of the samples stop participating in the research for some reason, they will be removed and other samples will be selected and replaced in their place. Also, the condition of the wound is checked for the presence of granulation tissue and epithelization every time the dressing is changed. If signs of infection are observed, the sample will be removed from the study and referred to the doctor for further treatment. In order to increase the accuracy and accuracy of the research, two observers (the researcher and the permanent nurse who changes the dressing) will be used before the study and compared in the observed position. In addition, in each session, with the consent of the patient, photographs are taken of the lesions and they are examined in terms of the healing process. In this study, patients, caregivers, researchers and the person responsible for the analysis will not know the type of intervention for each person or group.
Category
Treatment - Drugs

2

Description
Control group: The studied patients were dressed with 1% silver sulfadiazine by the researcher once a day for a period of 14 days. The control group is treated only with 1% silver sulfadiazine. In this way, after washing the wounds daily with normal saline, in second-degree superficial wounds that usually have a complete blister, without removing the blister in the control group, a layer of 1% silver sulfadiazine cream with a diameter of 5 mm will be placed on the wound. And it is bandaged. In a second degree deep wound where the blisters are usually destroyed, after removing the blisters and dead tissues and washing the wound surface with normal saline in a sterile way and placing a layer of pumpkin seed oil with a diameter of 5 mm on the wound, a bandage is applied. be made patients in six stages; The first session before the start of treatment, the third day, the seventh day and the day of the clear start of epithelization, the day of recovery and the fourteenth day after the start of treatment are evaluated, and the day of the clear start of epithelization and the start of the repair process will be recorded for each patient. To check the condition of the wound, they are evaluated during the study and every time the dressing is changed. If any of the samples stop participating in the research for some reason, they will be removed and other samples will be selected and replaced in their place. Also, the condition of the wound is checked for the presence of

granulation tissue and epithelization every time the dressing is changed. If signs of infection are observed, the sample will be removed from the study and referred to the doctor for further treatment. In order to increase the accuracy and accuracy of the research, two observers (researcher and a permanent nurse changing the dressing) will be checked and compared before the study, in the observed position. In addition, in each session, with the consent of the patient, photographs are taken of the lesions and they are examined in terms of the healing process. In this study, patients, researchers, nurses and the person responsible for the analysis will not know the type of intervention for each person or group.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ayatollah Kashani hospital

Full name of responsible person
Maede Barati

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Yasouj University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Yasouj University of Medical Sciences

Full name of responsible person
Mohsen Salari

Position
Assistant Professor

Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Part of the data related to the main outcome will be shared
When the data will become available and for how long
Access to data six months after completion of collection and results
To whom data/document is available
Access to data through academic institutions
Under which criteria data/document could be used
Research works and references
From where data/document is obtainable
Yasuj University of Medical Science, Faculty of Nursing
What processes are involved for a request to access data/document
Access after going through the relevant administrative procedures
Comments